Service Guide for Administrative Licensing Matters Regarding the Preservation of Human Genetic Resources in China

I. Scope of Application This license applies to the preservation of human genetic resources, Activities that provide a basic platform for academic research.

Human genetic resource preservation activities refer to the act of preserving human genetic resources with legal sources under suitable environmental conditions to ensure their quality and safety for future scientific research. It does not include temporary storage for teaching purposes, after laboratory testing, in accordance with legal and regulatory requirements or clinical research protocols.

If the human genetic resource preservation activities that require administrative approval also involve the collection of human genetic resources, the applicant only needs to apply for an administrative approval for the preservation of human genetic resources and does not need to apply separately for an administrative approval for the collection of human genetic resources.

Human genetic resource materials include all types of cells, whole blood, tissue/tissue sections, semen, cerebrospinal fluid, pleural/peritoneal effusion, blood/bone marrow smears, hair (with hair follicles), etc. Other human secretions, body fluids, swabs, etc. that do not contain cells do not need to be reported. Human genetic resource information includes data information such as genes, genomes, transcriptomes, epigenomes, and nucleic acid biomarkers such as ctDNA, as well as information related to diseases, races, etc. related to this data. Other data types that do not contain human genetic resource gene information do not need to be reported. For the needs of clinical diagnosis and treatment, blood collection and supply services, investigation and punishment of crimes, doping testing, funeral and burial activities, the use of my country's human genetic resources for preservation activities shall be carried out in accordance with relevant laws and administrative regulations and are not within the scope of application of this license.

Inside.

2. Information

(1) Item Name: Approval for the Preservation of Human Genetic Resources in China. (2) Approval

Category: Administrative License.

3. Basis for handling

1. Biosafety Law of the People's Republic of China 2. Regulations of

the People's Republic of China on the Administration of Human Genetic Resources 3.

Implementation Rules of the Regulations on the Administration of Human

Genetic Resources 4. Administrative Licensing Law of the People's Republic of China

IV. Acceptance Agency

National Health Commission

V. Decision-making Body

National Health Commission

6. Quantity Restriction No

quantity restriction

7. Service Requirements

(1) Applicant requirements

A Chinese entity with legal person status.

(2) Approval conditions

1. Applicants for the preservation of human genetic resources in China should meet the following requirements:

The following

conditions must be met: (1) the entity must be

a legal person; (2) the preservation purpose must be clear and

legal; (3) the preservation plan must be reasonable;

(4) The source of the human genetic resources to be preserved is legal; (5) It has

passed the ethical review; (6) It has a

department responsible for the management of human genetic resources and a preservation management system.

degree;

(7) Comply with national technical specifications and requirements for the preservation of human genetic resources

places, facilities, equipment and personnel.

2. Prohibition requirements: The application for the preservation of human genetic resources in my country,

Applications that do not meet the above conditions will not be approved.

(3) Types of matters to be handled

1. Before

starting any new human genetic resource preservation activities in my country that provide a basic platform for scientific research,

an administrative application should be submitted to the National Health Commission.

license.

2. If the

applicant for change has obtained the administrative license for preservation activities in accordance with the law, and there is a

change in major matters such as the preservation purpose, preservation plan or preservation content, the licensee shall submit an

application for change to the National Health Commission.

3. Renewal If

the licensee needs to extend the validity period of the administrative license, he/she shall apply to the National Health Commission

thirty working days before the expiration of the validity period of the administrative license. The National Health Commission shall make a

decision on whether to grant the extension based on the application of the licensee before the expiration of the validity period of the

administrative license; if no decision is made within the time limit, the extension shall be deemed to be granted. 4. Revocation

In any of the following circumstances, the National Health Commission shall, upon request of the interested party, The administrative license for human genetic resources may be revoked upon request or based on authority:

(1) Abuse of power or dereliction of duty in making a decision to grant an administrative license; (2) Exceeding statutory authority in making a decision to grant an administrative license; (3) Violating statutory procedures in making a decision to grant an administrative license; (4) Granting an administrative license to an applicant who does not have the qualifications to apply or does not meet statutory requirements; (5) Other circumstances under which the administrative license may be revoked according to law.

If the licensee obtains the administrative license by fraud, bribery or other improper means, The National Health Commission should be abolished.

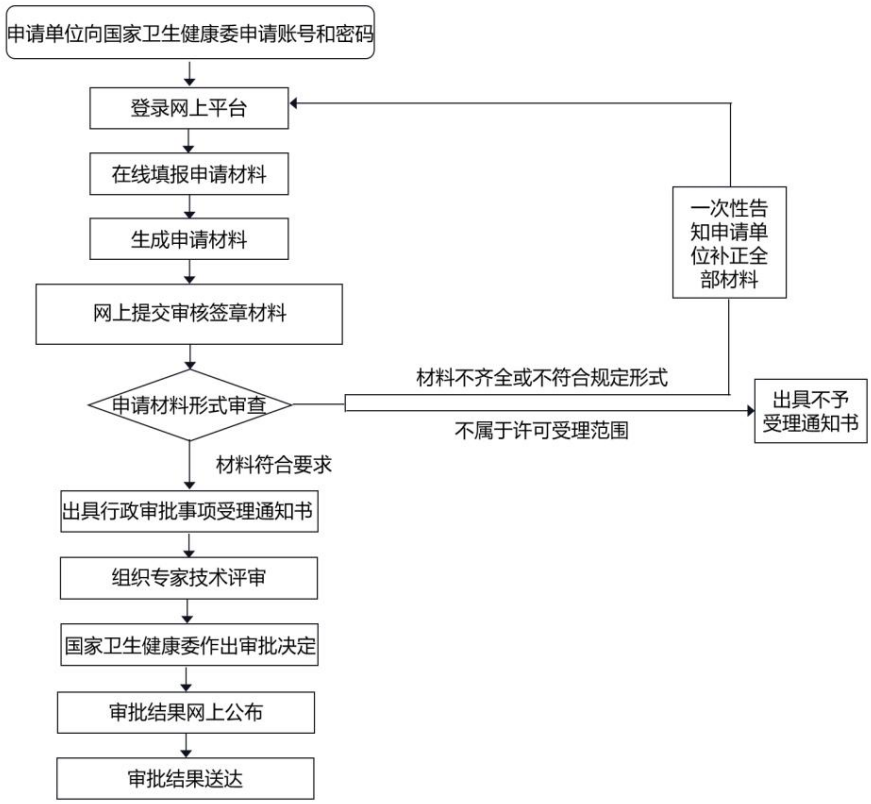
If the revocation of an administrative license in accordance with the provisions of the preceding two paragraphs may cause significant damage to the public interest, it shall not be revoked.

5. Annual Report: Human genetic resource depositories shall submit to the National Health Commission an annual report on their human genetic resource deposits for the previous year in accordance with Article 15 of the Regulations of the People's Republic of China on the Administration of Human Genetic Resources. Where the depositories have been licensed for less than one year, they shall submit the annual report for the following year. The annual report shall include the following information:

(1) The status of preserved human genetic resources; (2) Information on the sources and use of human genetic resources; (3) The implementation of relevant management systems for the preservation of human genetic resources; (4) The maintenance and changes of the premises, facilities, and equipment used by the unit for the preservation of human genetic resources;

(5) Changes in the main management personnel responsible for preservation work in the unit.

(IV) Application process



Note: If the applicant withdraws the application in writing before the administrative licensing decision is made,

The National Health Commission terminates the review of administrative license applications.

8. Online Application Materials

Serial number	Name of electronic materials submitted	Require
1	application	Fill in the online platform
2	Legal person qualification materials	Legal person qualification materials such as business license of corporate legal person, legal person certificate of public institution or registration certificate of private non-enterprise unit should be uploaded as attachments to the application form.
3	Text of the Informed Consent Form	Upload as an attachment to your application
4	Ethical review approval	The ethics review document should include review opinions, a list of review materials, a signature and seal page, an attendance sheet for ethics committee members, etc. If the review materials involve version numbers and version dates, they should be noted and uploaded as attachments to the application.

5	Preservation Plan	The preservation plan includes but is not limited to the preservation purpose, preservation process, preservation plan, etc. The preservation management
6. Preservation Management System		system, which is uploaded as an attachment to the application, includes but is not limited to the management mechanism and job responsibilities, sample storage and outbound management system, human genetic resource registration, processing, use record and archive management system, personnel training system, safety management system, confidentiality management system, emergency plan and disposal plan, etc. The preservation
7 Deposit of technical documents		technical documents, which are uploaded as an attachment to the application, include but are not limited to facility and equipment management requirements, site environment management requirements, personnel allocation, technical operation specifications and quality control system documents, etc.
8	Materials proving the legal origin of human genetic resources	Upload as an attachment to your application
9	Storage location layout Floor Plan	If applicable, please upload it as an attachment to the application form.
10 Other supporting documents		If applicable, please upload it as an attachment to the application form.

IX. Application for Acceptance

Electronic application materials are received through an online platform. The platform website is: https://www.hgrg.net/loginÿ

10. Application Methods

This administrative license is handled in accordance with the general procedures, including application, acceptance, technical Review, decision and delivery of documents, etc.

(1) Online application

The administrator of the application unit (legal person account) creates a new project and authorizes the applicant (natural person account), who then logs into the system and fills in the project. The applicant completes the application and submits it to the administrator for review. After verification, the application materials are generated and the application is directly

Download and upload the signed and stamped review opinion, and then the unit administrator submits the formal application.

(2) Acceptance

If the applicant's application materials are complete and in the required form, the National Health Commission shall accept the application and issue a paper or electronic certificate with a special seal and date. If the application materials are

incomplete or do not comply with the legal form, the National Health Commission shall inform the applicant of all the necessary supplements within five working days of receiving the formal application materials.

(3) Technical review

The National Health Commission entrusts the China Biotechnology Development Center to organize experts to conduct technical reviews of accepted applications and form expert review opinions as a reference for making administrative licensing decisions.

(4) Approval decision

The National Health Commission will make a decision to approve or disapprove based on the review results.

Certainly.

(V) Announcement of Results

The decision to grant administrative license made by the National Health Commission will be

The information will be made public on the website of the National Health Commission.

(6) Service

The National Health Commission will deliver the approval decision letter to the address or email address/ website designated by the applicant by mail or electronic delivery within 10 working days, and will also copy it to the human genetic resources authorities of the provincial, autonomous regional, and municipal people's governments. The applicant can check the delivery status in the application system.

11. Administrative License

China's human genetic resources preservation approval decision.

12. Approval Time Limit

The National Health Commission will make a decision to approve or disapprove within 20 working days of formally accepting an application. If, due to special reasons, the approval decision cannot be made within the prescribed time limit, an extension of 10 working days may be granted with the approval of the head of the National Health Commission. If the National Health Commission makes an administrative licensing decision that requires a hearing, inspection, testing, quarantine, appraisal, or technical review, the time required will not be counted within this time limit, but the applicant will be notified of the required time in writing.

13. Approval Fees: There is no

fee for this approval matter.

14. Rights and Obligations of Applicants

(1) In accordance with the Administrative Licensing Law of the People's Republic of China, the Regulations of the People's Republic of China on the Administration of Human Genetic Resources and the Implementation Rules of the Regulations on the Administration of Human Genetic Resources, applicants shall enjoy the following rights in accordance with the law: 1. They shall have the

right to make statements and defenses regarding the administrative licenses implemented by administrative agencies; if their legitimate rights and interests are damaged due to the illegal implementation of administrative licenses by administrative agencies, they shall have the right to demand compensation in accordance with the law.

2. If the applicant has any objection to the approval decision, he or she may apply for administrative reconsideration to the National Health Commission within 60 days from the date of receipt of the notice, or may file a lawsuit with the People's Court within 6 months from the date of receipt of the notice.

(2) In accordance with the Administrative Licensing Law of the People's Republic of China, the Regulations of the People's Republic of China on the Administration of Human Genetic Resources, and the Regulations on the Administration of Human Genetic Resources

The "Implementation Rules" stipulate that when applying for administrative licenses, applicants shall truthfully submit relevant materials to the administrative authority and reflect the actual situation, and shall be responsible for the authenticity of the substantive content

of their application materials. If an applicant engages in fraud or other acts during the administrative application process, the National Health Commission will terminate the review of its application or revoke the approval decision made, notify its competent department in writing, and, depending on the circumstances, investigate its liability in accordance with the "Administrative Licensing Law of the People's Republic of China", "Administrative Penalty Law of the People's Republic of China", "Regulations of the People's Republic of China on the Administration of Human Genetic Resources" and "Implementation Rules of the Regulations on the Administration of Human Genetic Resources".

15. Consultation Channels

(1) Window consultation: China Center for Biotechnology Development (Address: 1st Floor, Building 4, No. 16, West Fourth Ring Road, Haidian District, Beijing); (2) Email consultation: ycb@cncbd.org.cn; (3) Telephone consultation: 010-88225151/88225168. (4)

Consultation hours: 8:30-11:30 and 13:30-16:30 on weekdays.

16. Supervision, Complaint and Reporting Channels

(1) Telephone complaints: National Food Safety Risk Assessment Center Discipline Inspection and Supervision Room 010-52165515;

(2) Email complaints: jishenchu@cfsa.net.cn; (3) Letter complaints: Discipline

Inspection and Supervision Department of National Food Safety Risk Assessment Center Room 2, Building 2, No. 37 Guangqu Road, Chaoyang District, Beijing, China (Postal Code: 100022).

17. Public Inquiry

After 20 working days from the date of acceptance, you can

The query results can be obtained from the National Health Commission's website or the service system.